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10/735,271	12/12/2003	Tomomi Sugiyama	11333/31	3598

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EXAMINER	
WRIGHT, PATRICIA KATHRYN	
ART UNIT	PAPER NUMBER
1797	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,271	SUGIYAMA, TOMOMI	
	Examiner	Art Unit	
	P. Kathryn Wright	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed May 07, 2009 in which claims 1 and 12 were amended. The amendments have been thoroughly reviewed and entered. Any objection/rejection not repeated herein has been withdrawn by the Office.

Claims 1-19 are currently under prosecution.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "analyzer code" in claims 1 and 12. While the specification appears to provide antecedent basis for an "analyzer specification code" for specifying the type of analyzer used, the specification does not disclose an "analyzer code".

The rules of the PTO require that application claims must "conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." 37 CFR 1.75(d)(1).

As Applicant appreciates, the terminology of the original claims follows the nomenclature of the specification, but sometimes in amending the claims or in adding new claims, new terms are introduced that do not appear in the specification. The use of a confusing variety of terms for the same thing should not be permitted. New claims and amendments to the claims already in the application should be scrutinized not only for new matter but also for new terminology. While an applicant is not limited to the

nomenclature used in the application as filed, he or she should make appropriate amendment of the specification whenever this nomenclature is departed from by amendment of the claims so as to have clear support or antecedent basis in the specification for the new terms appearing in the claims. This is necessary in order to insure certainty in construing the claims in the light of the specification. See 37 CFR 1.75, MPEP §608.01(i) and § 1302.01. Note that examiners are to ensure that the terms and phrases used in claims presented late in prosecution of the application find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description, see 37 CFR 1.75(d)(1).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 2, 11, 12, and 19 are again rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a database containing the degree of dilution of the sample.

Claims 1 and 12 recite a computer for correcting the result when the analyzer does not have a dilution mode and the sample is a diluted. However, in order to calculate the correct assays result, the computer would require the degree of dilution of the sample stored in the database beforehand.

Applicant is reminded that the structure that goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-9 and 12-19 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Admissions by Applicant in view of Mandler et al., (US Patent No. 6,275,150), hereinafter "Mandler".

Applicant's original specification at page 3, line 17- page 4, line 7 discusses what is known in the prior art. That is, Applicant admits in recent years analyzers capable of assay mode selection, which perform assays by selecting between a normal mode for assaying normal samples and a dilution mode for assaying dilute samples are known. When performing an assay in the normal mode, the assay is performed using a normal sample which is not diluted, and the obtained assay result is output. However, when performing an assay in the dilution mode, a dilute sample is prepared by diluting a

sample to a predetermined degree and performing the assay. The analyzer then corrects the obtained assay result based on a predetermined degree of dilution stored in database beforehand, and this corrected assay result is output as the final assay result. If this analyzer is connected to the system (i.e., management system), the assay result is automatically input to the system (online input).

Applicant further admits when a dilute sample is assayed using an analyzer which does not have a dilution mode and the assay result is input to the clinical laboratory management system, the assay result is not automatically input from the analyzer to the management system (online input), but rather is input by the following procedure. First, the assay is performed using an analyzer. Then, a laboratory technician performs corrective calculations on the assay result. The corrected result is then manually input (offline input) to the system from an input terminal as the final assay result.

Therefore, the only difference between the known prior art as admitted by Applicant and that claimed, is the use of a computer for performing the corrective calculations on the assay result previously performed by a laboratory technician. However, the use of a computer for performing the corrective calculations on the assay result is well known in the art, see for example Mandler.

Applicant is reminded that admission by Applicant in the specification constitute as prior art which can be relied upon for both anticipation and obviousness determinations, regardless of whether the admitted prior art would otherwise qualify as prior art under the statutory categories of 35 U.S.C. 102. See MPEP 2129 (I) and (II), and 706.02 (III). See also *Riverwood Int 'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346,

1354, 66 USPQ2d 1331, 1337 (Fed. Cir. 2003); *Constant v. Advanced Micro-Devices Inc.*, 848 F.2d 1560, 1570, 7 USPQ2d 1057, 1063 (Fed. Cir. 1988).

Mandler teaches a clinical laboratory management system comprising a plurality of analyzers 20a-c for analyzing samples outputting a result of an assay (see Fig. 16) and a management apparatus connected to the analyzers through a network 30 (see Fig. 1). The management apparatus of Mandler comprises at least one database in the computer 10. Note that all computer memory (i.e., a database) is configured for storage, thus, the storage in the reference need only be capable of storing the same type of data (i.e., dilution rate and sample identification information). Nevertheless, Mandler does in fact teach a database configured to store a result of the assay output from the analyzers, analyzer identification information (e.g., ADVIA2, ADVIA3, etc), and the sample identification information including whether or not the pre-dilution module 24 performs any dilution or whether it is required (see col. 3, line 20- col. 4, line 7).

The management apparatus of Mandler also includes a computer 10 configured for determining whether the analyzers have a dilution module 24 in which the dilution mode (PD) is in the "READY" or "OFF" state, as indicated by the status buttons 288, see Fig. 5 and col. 6, lines 6-60. That is, Mandler teaches a system where one of the analyzers 20a-c connected through a network can be in the "OFF" state (i.e., no dilution mode) and the other analyzer is available (i.e., has a dilution mode). The computer uses a previously stored dilution rate of the sample to calculate the result of the sample used in the assay (see "Dil" column in Fig. 16 and col. 13, lines 11-41). The computer displays various screens (GUI) designed to receive, among other things, the quantity of the sample used in the assay and the assay results determined by the computer.

Mandler also teaches a printing device (printer 12). Since all printers are configured for printing, the printer in the reference need only be capable of printing the same type of data (i.e., dilution rate and sample identification information).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a computer to perform the corrective calculation on the assay of a diluted sample when the analyzer is not in a dilution mode since this reduces the likelihood of operator error. Further, it has been held that providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. *In re Venner*, 120 USPQ 192.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Admissions by Applicant in view of Mandler et al., (US Patent No. 6,275,150), as applied to claim 9 above, in further view of EP 1 107 159 to Okuno et al., (hereinafter "Okuno").

The teachings of Applicant and Mandler have been summarized above. While Mandler does teach a screen for receiving sample identification information, Mandler does not explicitly teach the sample information is printed as a bar code. However, the use of bar codes for storing sample information in an analyzer system is considered conventional, see for example Okuno.

The teachings of Okuno have been summarized in the previous Official action, dated June 05, 2007. Okuno teaches a clinical laboratory management system comprising a plurality of analyzers 2 for analyzing samples and a management apparatus connected to the analyzers (see Fig. 1). The management apparatus of

Okuno comprises, *inter alia*, sample identification information printed as a bar code (see par. 0091]).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to supply the sample identification information of in the combined system of known prior art and Mandler in the form of a bar code, as taught in Okuno, since bar codes are generally not readable by humans, therefor can be used to provide patient anonymity.

Response to Arguments

9. First, please note that Applicant's request for a personal interview contained in an outstanding response is improper. It is Office policy to schedule a personal interview well in advance with the Examiner. Interviews should be scheduled prior to, or immediately following, the filing of a response by Applicant. Furthermore, 37 CFR 1.133 states, in part, when applicant is initiating a request for an interview, an "Applicant Initiated Interview Request" form (PTOL-413A) should be submitted to the examiner prior to the interview in order to permit the examiner to prepare in advance for the interview and to focus on the issues to be discussed. This form should identify the participants of the interview, the proposed date of the interview, whether the interview will be personal, telephonic, or video conference, and should include a brief description of the issues to be discussed. See MPEP 713.01 (111). Applicant's request for a personal interview at least fails to propose a date for the personal interview in advance with the Examiner and does not include a brief description of the issues to be discussed.

Applicant's arguments filed May 07, 2009 have been fully considered but they are not persuasive.

In response to the previous rejection of claims 1, 2, 11, 12, and 19 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements, applicant argues independent claims 1 and 12 recite a computer "configured for" correcting the result when the analyzer used in the assay does not have a dilution mode, is in and of itself, a complete and operative device. Applicant asserts that a computer so "configured" will possess necessary data structure or "functional descriptive material" as defined in MPEP 2106.01 to perform the recited operation.

The Examiner does agree that the computer is not missing the necessary data structure or "functional descriptive material". In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) However, the Examiner asserts that the independent claims are omitting a database containing the degree of dilution of the sample. While the independent claims recite a computer for correcting the result, when the analyzer does not have a dilution mode and the sample is a diluted, the computer would require the degree of dilution of the sample stored in the database beforehand in order to calculate the correct assay result and, thereby present a complete operative device. The "functional descriptive material" of a computer includes data structures

and computer programs that impart functionality when employed in a computer, however, "functional descriptive material" in a computer does not include the database storage containing the dilution rate.

In response to the previous rejection of claims 1-9, and 12-19 under 35 U.S.C. 103(a) as being unpatentable over Admissions by Applicant in view of Mandler (US Patent No. 6,275,150), Applicant argues each of the biomedical analyzer instruments (Advia instruments) 20a- 20c described in Mandler contains a pre-dilution/ISE module 24 (col. 3, lines 52- 54). Thus, Applicant asserts the type of corrective calculation in Mandler is limited to assay results obtained from analyzers with a dilution mode. Applicant concludes that neither Mandler nor the background section of Applicant's specification teach or suggest "a computer configured for...correcting the result when the analyzer used in the assay does not have a dilution mode", as required by independent claims 1 and 12.

The Examiner respectfully disagrees. The above referenced rejection does not rely on Mandler for teaching a computer for performing corrective calculation of an assay obtained from an analyzer without a dilution mode, rather the Examiner relies upon Applicant's specification, which states is it well known in the prior art for a laboratory technician to perform corrective calculations on an assay result when a dilute sample is assayed using an analyzer that does not have a dilution mode. Mandler is relied upon for teaching the use of computer for performing the corrective calculation on an assay result using a diluted sample. It would have been obvious to the skilled artisan to use a computer to perform the corrective calculations on the assay of a diluted sample since this reduces the likelihood of operator calculation error. In addition, one

cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Also note that Mandler teaches a clinical laboratory management system comprising a plurality of analyzers 20a-c for analyzing samples outputting a result of an assay (see Fig. 16) and a management apparatus connected to the analyzers through a network 30 (see Fig. 1). The management apparatus of Mandler comprises at least one database in the computer 10 and database is configured to store a result of the assay output from the analyzers, analyzer identification information (e.g., ADVIA2, ADVIA3, etc), and the sample identification information

Thus, for the reasons delineated above, the claims remain rejected over the prior art.

Conclusion

10. No claims allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is (571)272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. Kathryn Wright/
Examiner, Art Unit 1797